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10/065,279	09/30/2002	Jeffrey C. Leung	2284.40533	5693
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ANGIOTECH P. O. BOX 2840 NORTH BEND, WA 98045			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 08/18/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

angiotechpatents@angio.com  
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### Office Action Summary

**Application No.**

10/065,279

**Applicant(s)**

LEUNG ET AL.

**Examiner**

TUAN V. NGUYEN

**Art Unit**

3731

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58, 60 and 63-140 is/are pending in the application.
- 4a) Of the above claim(s) 37-57 and 63-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36, 58, 60 and 102-140 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 and 16 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-58, 60 and 63-140 are pending in this present application. In previous Office action claims 1-36, 58, 60 and 102-140 were examined and rejected and claims 37-57 and 63-101 were previously withdrawn due to restriction requirement.
2. This Office action is in response to the amendment filed on 06/01/10.

### ***Terminal Disclaimer***

3. The terminal disclaimer filed on 06/01/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on the copending Application No. 10/065280 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Amendment and Arguments***

4. The terminal disclaimer filed on 06/01/10 has been reviewed and is accepted. Therefore, the double patenting rejection has been withdrawn.
5. Applicants' arguments filed on 05/19/10 with respect to the rejection of claims 1-3, 5-9, 10, 12, 14-21, 23-30, 32-36, 58, 60 and 102-114 under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) in view of Morency et al. (US 2003/0149447) have been fully considered but they are not persuasive.
  - a. In page 3 of the remarks applicants argue that "Applicants respectfully point out that Morency contains no mention at all of the barb base.

Accordingly, there is no teaching or disclosure in Morency directed to the impact that various barb base configurations may have on the performance properties of a barbed suture. Furthermore, it should be noted that Morency, even though interested in preventing tearing of delicate tissue, never mentions that the barb base should be configured in any particular way in order to minimize or otherwise impact the tearing of delicate tissue, including having the barb base be in an arcuate shape. The rejection seems to assume a connection between the shape of the underside of the barb, and the shape of the barb base. However, there is no logical reason why that connection should exist, and there is nothing in the cited prior art to suggest or support that possible connection. Thus, it would appear that the Examiner has used hindsight and supposition to create this rejection, rather than drawing from any teaching or suggestion in Morency". Examiner respectfully traverses applicants' remarks. In paragraph [0040] Morency specifically discloses "FIG. 1G shows an enlarged fragmentary view of a portion of another alternate barbed surgical suture 70. In this embodiment, the **barbs 72 are rounded on both the leading edge 74 and trailing edge 76**. The rounded barbs 72 may be used in situations with delicate tissue, which is prone to tearing. The rounded barbs 72 allow the barbed surgical suture 70 to enter the tissue and hold with a minimal amount of tearing of the tissue". Fig. 1G shows the leading edge 74 and trailing edge 76 extend to the base of the

barb. Based on Fig. 1G and the passage above, Examiner contends that Morency discloses the tip and the base of the barb are rounded to prevent tearing of delicate tissue.

- b. In pages 3-4 of the Remarks, applicants argue that "Figures 15 and 16 are discussed at column 8 of Buncke. Applicants have reviewed the entirety of column 8 and do not see any discussion, or even any mention, of the angle of the blades used to cut a barbed suture. Furthermore, there is no mention of the angle of the barbs created by action of the blades. In looking at the Figures themselves, these are clearly schematic drawings, intended to convey and support the general topics discussed at column 8. Those topics do not include barb cut angle. In view of this silence on the part of Buncke, Applicants respectfully contend that neither the text nor the supporting drawings teach or suggest to specify barb cut angle as a feature of a barbed suture, and certainly do not teach or suggest the ranges set forth in Applicant's claimed invention". Examiner respectfully traverses applicants' remarks. Figures 15 and 16 of Buncke show the barb, 98, being made from a blade that is characterized by having a sharp cutting edge, a base and an angle. Thus, Buncke inherently discloses the barbs created from the blade must have a thickness, length, thus, the blade has a barb cut angle. Based on the disclosure of Buncke, Examiner contends that it would be obvious to select any of about 140 to 175 degrees, or about 152 to 165 degrees or about 152 to 163 degrees as the

barb cut angle because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

6. Applicants' arguments filed on 05/19/010 with respect to the rejection of claims 4, 13, 22, 31 and 115-140 under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and Morency et al. (US 2003/0149447) and further in view of Ruff (U.S. 5,342,376) have been fully considered but they are not persuasive. In page 5 of the Remarks, applicants' argue that "Figure 4 illustrates such barbs, and shows multiple barbs arising from a single location on the connector, where the barbs point in different directions. Applicants respectfully contend that Ruff cannot mean to combine the disclosure of col. Lines 5-17 with this disclosure at col. 5, lines 2-6 because the resulting connector would provide "soft tissue" type barbs and "hard tissue" type barbs at the same location. The tissue itself, when the connector was inserted into the tissue, would be either soft or hard at this location of the connector, and surely not both types. Thus, given the rationale of Ruff for selecting a barb type to match the tissue type, it would not be logical to prepare a connector of the sort shown in Fig. 4 having two different types of barbs". Examiner respectfully traverses applicants' remarks. Fig. 11 of Ruff's drawings shows the suture is used to close an incision in the skin. Note that the skin includes fatty layer, cutaneous layer, and subcutaneous layer. In order to have a secure closure, the suture must pass through these layers. Based on the disclosures in column 4, lines 5-20 and column 5, lines 2-6, one of ordinary skill in the art would recognize

that the barbed suture should include at least a set having a barb size different from the barb size of the other set for the purpose of effectively engaging with the different layers of tissue together.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. **Claims 1-3, 5-9, 10, 12, 14-21, 23-30, 32-36, 58, 60 and 102-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) in view of Morency et al. (US 2003/0149447).**
10. Referring to **claims 1-3**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the

body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke further discloses the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines 12-19). Buncke discloses the invention substantially as claimed except for disclosing (1) the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and (2) the barb cut angle ranging from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees.

- a. As to point (1), Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.
- b. As to point (2), Figures 15 and 16 of Buncke drawings show the barb 98, which created by cutting blade 92, wherein the blade has a sharp cutting edge, a base and an angle. Thus the barbs 98 of Buncke disclose the general condition of the barb cut angle  $\Theta$  on the suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut angle ranging



from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Referring to **claims 10-12**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5.
  - a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.

- b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines 12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
12. Referring to **claims 19-22**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having an elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5.
- a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74)

and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.

- b. As to point (2), noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material. (col. 8, lines 12-19). Further, Figures 15 and 16 of Buncke drawings show the barb 98 having a barb cut length, thus the barbs 98 of Buncke disclose the general condition of the barb cut length. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
13. Referring to **claims 28-30**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second

end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5.

- a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.
- b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material.(col. 8, lines12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

14. Referring to **claim 58**, since claim 58 is the combination of claims 1, 10, 19 and 28, Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
15. Referring to **claim 60**, since claim 60 is the combination of claims 1, 10, 19, 28, and a twist cut with a spirality angle  $\alpha$  ranging from about 5 degrees to about 25 degrees. Noting that Buncke also disclose the barbs can be positioned in a spiral pattern if desired (col. 9, lines 3-10), Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
16. Referring to **claims 5-8, 14-17, 23-26, and 32-35**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (col. 1, lines 20-25).

17. Referring to **claims 9, 18, 27, and 36**, Buncke discloses the barbs can be on opposed sides of the suture, staggered, and they can be positioned in a spiral pattern if desired (col. 9, lines 3-10).
18. Referring to **claims 102-114**, Buncke discloses the suture 10 has about 100 to 500 microns in diameter (col. 4, lines 55-60), thus Buncke discloses the suture 10 having circular cross-section.
19. **Claims 4, 13, 22, 31 and 115-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and Morency et al. (US 2003/0149447) as applied to claims 1, 10, 19, and 28 above and further in view of Ruff (U.S. 5,342,376).**
20. Referring to **Claims 4, 13, 22, and 31**, Buncke/Morency discloses the invention substantially as claimed except for each set having a barb size different from the barb size of the other set. However, Ruff discloses the configuration of barbs 6 and the surface area of the barbs can vary depending upon the tissue in which the barbed suture is used (e.g. if the barbed suture is intended for use in fatty tissue, which is relatively soft, the barbs can be made longer to increase the holding ability in the soft tissue) (col. 4, lines 5-17 and col. 5, lines 2-6). It would have been obvious to one of ordinary skill in the art to design the barbed suture of Buncke/Morency to have at least two sets, wherein each set having a barb size different from the barb size of the other set for the purpose as disclosed by Ruff so that it too would have the same advantage.

21. Referring to **claims 115-140**, Buncke/Morency discloses the invention substantially as claimed except for the cross section of suture body has a non-circular cross section. However, Ruff discloses a non-circular cross section shape (e.g. rectangular or hexagonal cross section) increases the surface area of the suture body and facilitates the formation of the multiple barbs on the suture body (col. 6, lines 18-28). It would have been obvious to one of ordinary skill in the art to incorporate the teaching of Ruff into the suture of Buncke/Morency so that it too would have the same advantage.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Genova et al. (U.S. 7,225,512) discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731

/AnhTuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
8/13/10